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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,200	04/09/2004	David Lentz	760-129 DIV/CIP/CON II	2373
23869	7590	07/13/2005		
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			EXAMINER GHERBI, SUZETTE JAIME J	
			ART UNIT 3738	PAPER NUMBER

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/822,200

Applicant(s)

LENTZ ET AL.

Examiner

Suzette J. Gherbi

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response dated 4/28/05 and terminal disclaimer dated 8/11/05 have been received in application serial number 10/822,200. All comments have been taken into consideration.

Priority

2. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). Therefore the priority date relied upon for 10/822,200 (the current application) will be from patent 6,428,571 filed 3/14/00 which is when "self-sealing" properties are introduced.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 29-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shanzer 4,619,641 in view of Parsons et al. 6,521,284. Shanzer discloses the invention as claimed comprising: a first tubular (11) structure having a first thickness/porosity; and a second tubular (13) structure having a second thickness/porosity wherein the tubular structure is disposed externally about the first tubular structure and a resealable layer (15) made of silicone (a polymer) which is interposed between the first and second tubular structures for the purpose chronic hemodialysis access (col. 1, lines 9-18, col. 2, line 65). While Shanzer does disclose a **PTFE** material (col. 2, lines 48, 51), Shanzer does not disclose the use of **ePTFE** or adherence or a flowable material. Parsons et al. teaches grafts (see figures 1-4) with self-sealing properties (col. 10, lines 64-67 to col. 11, lines 1-51), which utilize ePTFE (col. 9, lines 19-21); a hydrogel that contains water (which equates to the flowable gel, see col. 6, lines 30-33); and wherein the self-sealing material is disposed within a cavity such that the cross-linkable material is adjacent to layers (22) (see col. 5, lines 1-4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to exchange the PTFE material of Shanzer to the ePTFE (as taught by Parsons et al.) because the ePTFE exhibits a high level of porosity and biocompatibility. It also would have been obvious to create a self-sealing flowable layer that adheres to the first and second layers because the flowable gels are known to deform elastically and then recover to their original form which would aid in the production of attaching the gel to the layers of the graft.

Response to Arguments

5. Applicant's arguments filed 4/28/05 have been fully considered but they are not persuasive. Applicant contends/alleges that a *prima facie* case of obviousness has not been established because Schanzer does disclose or suggest tubes with porosity and that the wall thickness does not correlate to porosity.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case applicant's specification does not define the term porosity however the term porosity according the American Heritage Dictionary is the ratio of the volume of interstices of the material to the volume of its mass. It is obvious that because Schanzer utilizes the material Gortex which is PTFE (and admitted in applicant's response is ePTFE) that pores and porosity exist in the invention of Schanzer due to the nature of the ePTFE. It is also obvious (see figures 1 and 2 of '641) that because that different thicknesses are disclosed then different volumes of mass of the material are present. In other words because it is disclosed that one tube can be thicker or have more mass than the other tube that the tubes will have varying porosities.

7. The Parsons reference is utilized to teach the self sealing properties and not for the purposes addressed by applicant.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Termin et al. 6,890,351 ; Brauker et al. 6,517,571.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

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11. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Suzette J-J Gherbi
11 July 2005